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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,852	02/04/2004	Jeffrey W. Ruberti	42222-0006	9743

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EXAMINER	
EGWIM, KELECHI CHIDI	
ART UNIT	**PAPER NUMBER**
1713	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,852	RUBEF ETI ET AL.	
	Examiner	Art Unit	
	Dr. Kelechi C. Egwim	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *113-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *113-119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/02/2007 has been entered.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 113 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, 35 U.S.C. 103(a) as being unpatentable over Hyon et al., or Yamauchi et al., for reasons cited in previous actions.

5. Claims 113-119 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, 35 U.S.C. 103(a) as being unpatentable over Tanihara et al., Ku et al., Yao et al., or Okamura, for reasons cited in previous actions.

While Hyon et al., Yamauchi et al., Tanihara et al., Ku et al., Yao et al., or Okamura may teach the product to be prepared by a different process from that recited in the claims, the product is the same as, or an obvious variant of, the presently claimed product absent evidence that the particular process of making results in a materially different product. Even though product-by-process claims are limited and defined by the process, determination of patentability is based on the product itself. The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even thought the prior product was made by a different process. See In re Marosi, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

Response to Arguments

6. Applicant's arguments filed 03/02/2007 have been fully considered but they are not persuasive.

7. Firstly, regarding the Declaration filed 03/02/2007, applicant's declaration finds its bases in the term "injectable", as used in the present claims, being limited to being injectable through a 5.57 mm artifice under 11 lbs or a 20 cc syringe at 45psi. However,

nowhere in applicant's originally filed declaration is such a definition or limitation for "injectable", as it is used in the claims, to be found. Thus, the decoration is not commensurate in scope with what is actually being claimed. Applicant's claims do not have any such necessary limitations for the term "injectable".

Also, the concentration and type of hydropolymer used in the declaration are not commemorate in scope with independent claim 113.

8. Regarding Hyon et al., Ku et al., Yao et al., Okamura and Tanihara et al., the limitation that the hydrogel be prepared without "the physically cross-linked hydrogel is formed without chemical cross-linkers, irradiation or thermal cycling", this limitation refers to the process, which is not what is currently being claimed. Applicant still has not demonstrated that the process used in the references, even if different from that of applicant's, would necessarily result in products materially different from what is currently claimed and originally presented.

9. Regarding the PVA copolymer in Tanihara et al., contrary to applicant statements a PVA copolymer is still a PVA polymer and, in this case, still a PVA polymer hydrogel. The exclusion of PVA copolymers is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

10. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., wherein, the hydrogel is intended for injection into humans or other living subjects) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further, even if such an recitation of intended use where included in the claims, the claimed invention must still result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

11. Regarding the argument that some of the prior art hydrogels are solid and therefore not injectable, this argument is not persuasive as even the hydrogels in solid form can serve as intermediaries in order to inject the hydrogels. Prior art, such as Tanhara et al., Ku et al., Okamara and Hyon, teach the hydrogels in both liquid and article forms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kelechi C. Egwim whose telephone number is (571) 272-1099. The examiner can normally be reached on M-T (7:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCE

KELECHI C. EGWIM PH.D.
PRIMARY EXAMINER